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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018

26111 7590 11/06/2002

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EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/06/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,158

Applicant(s)

Gardella

Examiner

Eliane Lazar-Wesley

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 15-36 and 38-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) none is/are allowed.
- 6) ☒ Claim(s) 1-14 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. The reply filed July 23, 2002, has been entered.
2. Applicant's election without traverse of Group I, claims 1-14 and 37 in Paper No.17 filed 7/23/02 is acknowledged.

Specification

3. The specification is objected to, because SEQ ID No:3 and SEQ ID No:9 appear to be identical. Furthermore, SEQ ID No:6 appears to be identical to SEQ ID No:11, and SEQ ID No:5 appears to be identical to SEQ ID No:13. Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claims 7 and 8 are objected to as claiming identical sequences.
Claim 7 is claiming SEQ ID No:3, which is identical to PG5 of SEQ ID No:9 claimed in claim 8.
Claim 7 is claiming SEQ ID No:6, which is identical to PG7 of SEQ ID No:11 claimed in claim 8.
Claim 7 is claiming SEQ ID No:5, which is identical to PG9 of SEQ ID No:13 claimed in claim 8.

While amending the claims according to these objections and the rejections under 35 USC 112, second paragraph, below, Applicants are invited to be aware of potential duplicative claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

Art Unit: 1646

Claims 5, 6, 7, 11, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 6, 7, 12 lack antecedent basis for a polypeptide in claim 1.

Claim 11 is indefinite because, in f), the claim recites that B is "as...", and this does not provide defined metes and bounds for the structure of B.

Claim 14 is indefinite in the recitation of the Markush group for the nucleic acid sequences.

It is not clear why (SEQ ID No:16) is in parentheses, and if it is part of the Markush group.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-14 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising SEQ ID No:3, does not reasonably provide enablement for a compound that does not have biological activity, for a polypeptide comprising any linker, or any other variant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of the claims, 7) amount of

Art Unit: 1646

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-4, 6, 13 and 37 are directed to compounds comprising a linker of indefinite size and structure. Furthermore, in claims 1-5, 13 and 37, the B fragment is a binding portion of PTH, but the binding specificity is not defined. Claims 7, 8, 9 recite functional derivatives.

Claims 1-12, 14 and 37 are directed to a compound or polypeptide with no limitation regarding its biological activity. As claim 13 is to a biologically active polypeptide, it appears as if the compounds or polypeptides of claims 1-12, 14 and 37 would not be biologically active.

The specification does not provide adequate guidance regarding how to make functional species commensurate in scope with the claims, and how to use the non functional species. The specification does not provide guidance for linkers other than polyglycine, and for the scope of functional derivatives claimed.

Due to the large quantity of experimentation necessary to determine the size and structure of an appropriate linker , the lack of direction/guidance presented in the specification regarding the requirements regarding the linker and the binding portion of PTH required for an activity, the absence of working examples directed to linkers other than polyglycine, the complex nature of the invention, the level of skill of those in the art, the unpredictability of the effects of a linker positioned between the signaling domain and the binding domain of PTH on protein structure and function, and of the presence of any linker on the activity , and the breadth of the claims which fail to recite limitations such that the compound has a PTH biological activity , undue experimentation would be

Art Unit: 1646

required of the skilled artisan to make and/or use the claimed invention in its full scope, and one of skill in the art would not know how to use those embodiments that do not have biological activity. As claims 1 and 2 do not have a functional limitation, the depending claims 7-9 that recite a functional derivative are not enabled for their scope, because no function is associated.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

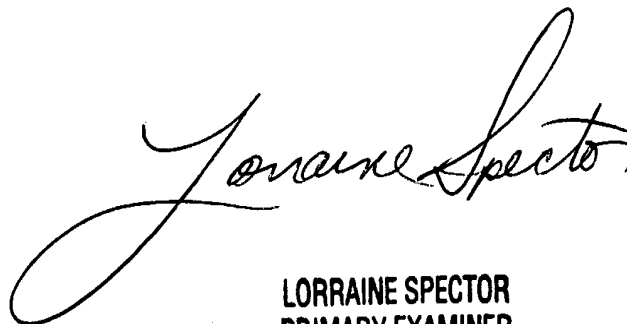
Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

October 21, 2002

ELW



LORRAINE SPECTOR
PRIMARY EXAMINER